

TRANSMITTAL LETTER TO THE
UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

1547/00268

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/509869

INTERNATIONAL APPLICATION NO. PCT/SE98/01982	INTERNATIONAL FILING DATE 3 November 1998	PRIORITY DATE CLAIMED 11 November 1997
TITLE OF INVENTION ARRANGEMENT FOR OBTAINING RELIABLE ANCHORING OF A THREADED IMPLANT IN BONE		
APPLICANT (S) FOR DO/EO/US Lennart Carlsson, Fredrik Engman, Roger Fromell and Lars Jörnéus		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. This is a **FIRST** submission of items concerning a filing under 35 U.S.C. § 371
2. This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. § 371.
3. This express request to begin national examination procedures (35 U.S.C. § 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. § 371(b) and PCT Articles 22 and 39(1).
4. A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. A copy of the International Application as published (35 U.S.C. § 371(c)(2)) WO 99/23971
 - a. is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. has been transmitted by the International Bureau.
 - c. is not required, as the application was filed in the United States Receiving Office (RO/US).
6. A translation of the International Application into English (35 U.S.C. § 371(c)(2)).
7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. § 371(c)(3))
 - a. are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. have been transmitted by the International Bureau.
 - c. have not been made; however, the time limit for making such amendments has NOT expired.
 - d. have not been made and will not be made.
8. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. § 371(c)(3)).
9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. A translation of the Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. (w/ references & Form PTO-1449)
12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. A **FIRST** preliminary amendment.
 - A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. A substitute specification.
15. A change of power of attorney and/or address letter
16. Other items or information:

Form PCT/IB/308 - Notice Informing The Applicant Of The Communication Of The International Application To The Designated Offices, Form PCT/RO/101 - PCT Request, Form PCT/IB/306 - Notification Of The Recording Of A Change, Form PCT/IPEA/409 - International Preliminary Examination Report w/amended claims & 4 sheets formal drawings

430 Rec'd PCT/PTO 03 APR 2000

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 09/509869	INTERNATIONAL APPLICATION NO. PCT/SE98/01982	ATTORNEY'S DOCKET NUMBER 1547/00268		
The following fees are submitted:		<input checked="" type="checkbox"/> CALCULATIONS <input type="checkbox"/> PTO USE ONLY		
Basic National Fee (37 CFR 1.492(a)(1)-(5)):				
Search Report has been prepared by the EPO or JPO	\$840.00			
International preliminary examination fee paid to USPTO (37 CFR 1.482)	\$670.00			
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))	\$760.00			
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO	\$970.00			
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)	\$96.00			
ENTER APPROPRIATE BASIC FEE AMOUNT =		\$970.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$130.00		
Claims	Number Filed	Number Extra	Rate	
Total Claims	12 - 20 =	0	X \$18.00	\$0.00
Independent Claims	1 - 3 =	0	X \$78.00	\$0.00
Multiple dependent claim(s)(if applicable)		+ \$270.00	\$	
TOTAL OF ABOVE CALCULATIONS =		\$1,100.00		
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28)		\$0.00		
SUBTOTAL =		\$1,100.00		
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$		
TOTAL NATIONAL FEE =		\$1,100.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +		\$0.00		
TOTAL FEES ENCLOSED =		\$1,100.00		
a. <input checked="" type="checkbox"/> A check in the amount of \$1,100.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No 22-0185 in the amount of \$0 to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No 22-0185 . A duplicate copy of this sheet is enclosed.				
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status				
SEND ALL CORRESPONDENCE TO: Pollock, Vande Sande & Amernick, R.L.L.P. 1990 M Street, N.W. Suite 800 Washington, DC 20036-3425		SIGNATURE <i>Elzbieta Chlopecka</i> 04-08-2000 Elzbieta Chlopecka, Reg. No. 32,767 NAME		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lennart Carlsson et al.

Serial No. Unknown

U.S. Patent Application of
PCT/SE98/01982

Filed: April 3, 2000

For: ARRANGEMENT FOR
OBTAINING RELIABLE ANCHORING
OF A THREADED IMPLANT IN BONE

Atty Docket: 1547/00268

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination and filing fee calculation, please amend the above-identified application as follows:

IN THE CLAIMS (Amended sheets):

Please amend the following claims:

Claim 3, line 1, delete "or 2";

Claim 7, lines 1-2, delete "or any of claims 5-6";

Claim 8, lines 1-2, delete "or any of claims 5-7";

Claim 9, lines 1-2, delete "or any of claims 5-8";

Claim 12, line 1, delete "or 11".

REMARKS

Claims 1-12 are pending in this application. By the foregoing amendment, claims 3, 7-9 and 12 have been amended to eliminate multiple dependencies and thus reduce the filing fee.

These amendments to the claims are not believed to introduce any new matter, and entry of this amendment is respectfully requested.

Favorable consideration of this case is respectfully requested.

Respectfully submitted,

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Date: 04-03-2000

WO 99/23971

09 / 509869

TITLE

ARRANGEMENT FOR OBTAINING RELIABLE ANCHORING OF A THREADED IMPLANT IN BONE

5

TECHNICAL FIELD:

The present invention relates to an arrangement permitting anchoring of a threaded implant in bone, for example dentine, in the human body by means of a screwing/tightening instrument. At its upper part, the implant has an anchoring hole for a unit, preferably in the form of a screw, intended to secure an element that can be attached to the implant and can in this case consist of a fixture holder, fixture, spacer, etc. The centre axis of the anchoring hole is also inclined in relation to the longitudinal axis of the implant.

The invention also relates to the use of an element, for example in the form of a fixture holder, fixture, spacer, etc., which can be attached to a threaded implant, where the implant is screwed into a bone, for example the dentine, by means of an instrument and where the implant has an anchoring hole for the securing unit, preferably in the form of a screw, for the element in question.

PRIOR ART

30 The invention is further concerned with the screwing functions of implants of the type described, inter alia, in Swedish Patent 9203563-3 and PCT application WO 96/18355. A characteristic of this type of implant is the presence of an inclined threaded hole which can 35 be arranged in a fixture for the implant or in the actual implant itself. The centre axis of the hole is inclined in relation to the axis of rotation of the implant. When anchoring further fixtures, spacers, etc. in the implant, an anchoring screw is used which can be

PCT/EP/2000/000000

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screwed tightly into the internal thread of the anchoring hole.

The said PCT document mentions the possibility of using
5 screwing instruments which are connected to the upper
parts of the implant for the purpose of screwing the
implant tightly into the bone in question.

DESCRIPTION OF THE INVENTION

10 TECHNICAL PROBLEM

A reliable and as far as possible simplified tightening function needs to be found. The invention is intended to solve this problem, among others.

15 The said PCT document proposes an instrument which uses the anchoring screw for securing a fixture to the implant. The instrument is provided with an inclined recess which coincides with or constitutes a
20 continuation of the anchoring hole. The anchoring screw is in this case removed first, and the instrument is applied in such a way that the recess of the instrument is arranged concentrically in relation to the recess in the implant, after which they can be screwed tight by
25 means of the said anchoring screw. When the implant has been tightened, the anchoring screw is loosened and removed, after which the instrument can also be removed. This procedure is a lengthy one. The inclined recess in the instrument is deep and problems can occur
30 during screwing, unscrewing, etc., of the anchoring screw in question. The present invention is intended to solve this problem too.

35 It may be desirable not to have to act on the anchoring screw during the tightening or screwing-in of the implant into the bone. The invention solves this problem too.

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SOLUTION

The feature which can principally be regarded as characterizing an arrangement according to the invention is, inter alia, that the element (fixture holder, fixture, etc.) that can be attached by means of the said unit (screw) is provided with means of cooperation with the instrument, and that the element and its means of cooperation are arranged to permit application of the instrument in a way which ensures that the axis of rotation of the instrument essentially coincides with the continuation of the axis of rotation of the implant.

An arrangement according to the invention can principally be regarded as being characterized by the fact that the tightening function exerted by means of the instrument is separate from the securing function exerted by means of the unit (screw) by virtue of the fact that the element (fixture holder, fixture, spacer, etc.) has a first portion via which the element is anchored by the anchoring unit in the implant, and a second portion which is separate from the first portion and which has cooperating means for the instrument.

Embodiments of the arrangement are specified in the attached subclaims.

The use according to the invention can principally be regarded as being characterized by the fact that the element (fixture holder, fixture, spacer, etc.) is used in the tightening operation with the instrument by virtue of the fact that the element has means cooperating with the instrument, to which means the instrument is applied with its axis of rotation essentially coinciding with the continuation of the axis of rotation of the implant.

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Further developments of the said use are specified in the attached subclaims.

ADVANTAGES

- 5 By means of what has been proposed above, a considerably simplified and less expensive tightening function is obtained for implants in dentine. The handling of small tightening screws can be avoided, and simple application to the implant for turning it or
10 screwing it in can be effected. The locking function for the instrument can be made extremely simple by the fact that a conventional locking screw can be used in a manner known per se. The implant with associated element, i.e. fixture holder, fixture, spacer, etc.,
15 can be supplied as one unit to which the tightening instrument can be applied in an extremely simple and effective manner.

DESCRIPTION OF THE FIGURES

20 A presently proposed embodiment of an arrangement and use having the significant characteristics of the invention will be described below with reference to the attached drawings, in which:

25 Figure 1 shows, in a vertical view and partial cross section, an implant which has been partially screwed into dentine by means of an instrument (screwing instrument),

30 Figure 2 shows, in a vertical section, and enlarged in relation to Figure 1, the implant together with a fixture holder screwed into the latter,

35 Figure 3 is a plan view of means which are arranged on the upper part of the fixture holder and can cooperate with the instrument,

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Figure 4 shows, in vertical section along the line A-A,
the design of the fixture holder,

5 Figure 5 shows, obliquely from above, the design of a
nut-shaped part on the implant, and

Figure 6 shows the upper parts of the implant from the
side, with the associated nut-shaped part according to
Figure 5.

10

DETAILED EMBODIMENT

In Figures 1 and 2, an implant is indicated by 1. The
implant is intended to be screwed into dentine 2, and

15 it can be screwed into a pre-drilled hole 3. The
implant can be of the self-tapping type and is in this
case provided with an external thread 1a. Attached to
the upper parts of the implant there is an element 4,
20 for example in the form of a fixture holder. This can
be attached or applied by means of a screw 5 or other
anchoring unit. An instrument, for example in the form
of a screwing instrument 6 with shaft-like part 6a and
handle part 6b, can be attached/applied to the upper
parts or portion 4a of the element. The instrument is
25 provided with a locking arrangement, for example in the
form of a locking screw 7. The fixture holder 4 is
provided with a second portion 4b which is separate
from the first portion 4a.

30 The axis of rotation (longitudinal axis) of the implant
is indicated by 1b, and the longitudinal axis or axis
of rotation of the screw 5 is shown by 5a. The implant
has an inclined, threaded recess 1c, in which the screw
5 can be screwed or the unit can be anchored. The
35 centre axis of the hole coincides with the centre axis
5a of the screw. The centre axis of the hole slopes at
an angle, for example an angle of about 45°, in
relation to the longitudinal axis 1b of the implant.
The said second portion 4b has a recess 4c which is

D E S C R I P T I O N

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concentric in relation to the recess 1c when the holder is in its secured position on the implant. The head 5b of the screw 5 is partially engaged in the recess 4c when the holder is in its secured position in the
5 implant.

The upper portion 4a of the holder 4 is provided with a key grip 4d. The holder 4 is additionally provided with a central recess 4e (can be threaded) which opens at
10 the top, and a transverse recess 4f in the bottom part of the recess. The centre line 4g of the holder coincides essentially with the axis of rotation 1b of the implant. The centre line of the hole 4e coincides with the centre line 4g of the holder 4. A shoulder
15 portion of the holder is shown by 4h. The upper part of the implant is shown by 1d.

Figure 3 shows a four-sided key grip for the instrument 6 which is provided with a corresponding internal four-
20 wall recess 6c (Figure 1). The key grip can have another number of sides, and the recess 6c likewise can have another number of corresponding walls. The part bearing the shoulder portion 4h can have a diameter of about 6 mm, and the external dimension d of the key
25 grip can be about 3.9 mm.

Figure 4 shows that the recess 4c passes into subsidiary recesses 4c' and 4c'', of which 4c' is threaded. The diameter of the recess 4c' is less than
30 the diameter of the recess 4c so as to form a shoulder 4c''' with which an underside 5b' (see Figure 2) of the screw 5 cooperates or on which it bears when the screw is in the screwed-in position. The holder 4 has an inclined surface 4i which slopes at an angle α of about
35 45° in relation to the axis 4g.

Figures 5 and 6 show the outer shape of the implant which in this case comprises a hexagonal nut 1c to which the holder 4 can be fixed in rotation by means of

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the recess 4c' which is designed with an internal hexagon shape corresponding to the outer shape of 1c. Other numbers of edges can be used.

- 5 The method can in this case be that the holder is first anchored to the implant by the recess 4c'' being brought over the nut shape 1c and the member 5 thereafter being applied and made fast (screwed). The instrument can thereafter be engaged on the four-edged
10 shape 4d via its corresponding four-edged recess 6d, after which the locking member 7 is activated (the locking nut is tightened). When the implant is screwed fully into the dentine 2, the locking member 7 is deactivated and the instrument 6 is removed from the
15 holder 4, which in this way can be left in place, i.e. the unit or the screw 5 does not need to be removed, screwed tight and once again removed in order finally to be screwed back again into the respective recess.
- 20 The new arrangement is thus characterized by the fact that the tightening function exerted by means of the instrument is separate from the securing function which is exerted by the said unit or screw 5. The said functions are attributable to different parts of the
25 holder, spacer, fixture, etc., which parts are thus separate or distinct. One element, for example in the form of a holder according to the above, can in this case be used in the screwing function by means of the instrument, the instrument being applied in such a way
30 that the instrument 6d coincides with the longitudinal axis 1b of the implant. Reference is made to Figure 1 where it can be seen that the direction of the longitudinal axis 6d of the instrument coincides with the continuations of the longitudinal axes 1b and 4g,
35 respectively, of the implant and of the fixture holder.

Figure 6 shows an inclined surface of the implant indicated by 1e. This surface slopes in relation to the longitudinal axis 1b of the implant by an angle α'

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which essentially corresponds to the angle α in Figure 4. The arrangement is also such that when the surfaces 4i and 1e bear against each other, the longitudinal axes 4g and 1b essentially coincide, which is also true 5 of the longitudinal axis 6d of the instrument since the key grip 4d is arranged concentrically around the longitudinal axis 4g of the holder.

The invention is not limited to the embodiment shown 10 above by way of example, but can be modified within the scope of the attached patent claims and the inventive concept.

ART 34 AMDT

PCT/SE98/01982

--PATENT CLAIMS

5

1. Threaded implant (3) for obtaining reliable anchoring in bone substance (1), preferably in the jaw-bone, in the human body, the bone substance being provided with a hole (2) in whose side wall (2b) it is possible to establish an internal threading (1a) which can cooperate with an external threading (3d, 3d') on the implant for reliable anchoring and healing-in of the implant in the bone substance, characterized in that the implant threading is arranged, particularly in the case of soft bone substance, to force the bone substance out in essentially radial directions (R) as a function of the extent to which the implant is screwed into the hole, that the implant threading has a slight conicity which extends along most or part of the length (L) of the implant and which cooperates with a circular cylindrical hole (2) in the bone (1) to effect greater forcing out of the bone substance at the outer parts (2c) of the hole than at the inner parts (2d), the degree of forcing out being adapted in relation to the softness of the bone substance in order to achieve the reliable anchoring, and that said conical threading comprises two or more thread spirals (thread entries) which, despite shortening the time for screwing the implant into the hole, provide a tight threading which permits effective integration with the bone substance during the healing-in process and counteracts deformation or breaking-up of fine bone trabeculae which surround the hole in the bone.

2. Implant according to claim 1, characterized in that the implant threading is arranged to ensure

DRAFTING DRAWING

AMENDED SHEET

that the pressure (P , P') between the bone substance and the implant has essentially a constant or slightly increasing value during the greater part of the operation of screwing the implant into
5 the hole.

3. Implant according to claim 1 or 2, characterized in that the front portion (tip) (3a) of the implant is designed with a conical thread (3e) which has a
10 conicity essentially exceeding the conicity of the slightly conical thread (3d).

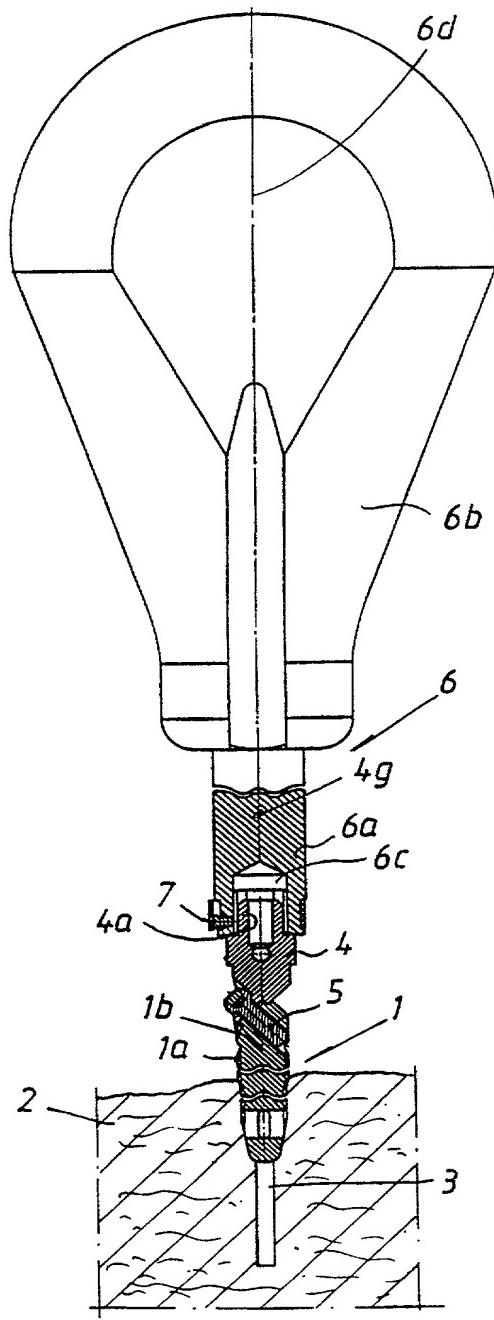
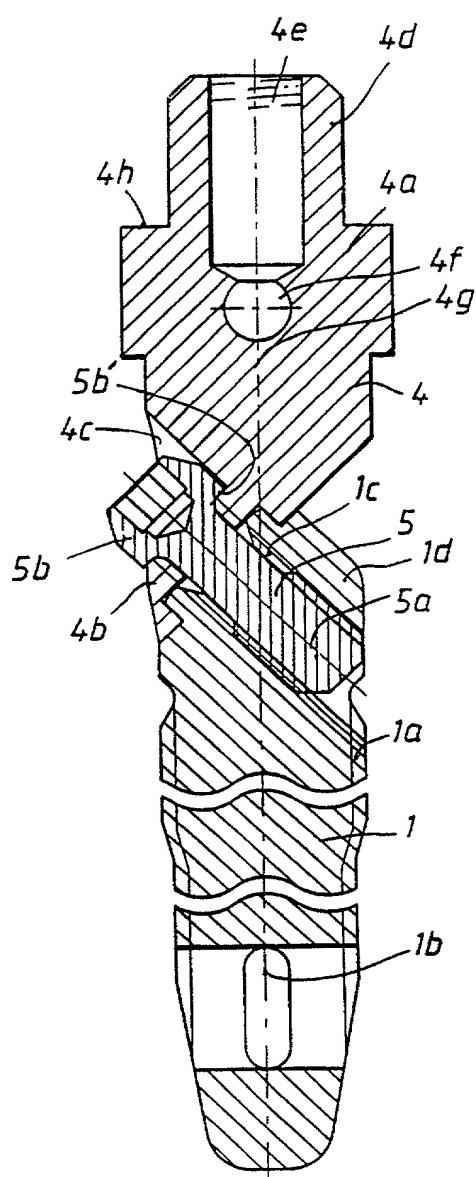
4. Implant according to claim 3, characterized in that the conicity of the slightly conical thread is
15 chosen between 0.1 - 0.4 mm or has an angle of inclination (α) of about 0.5 - 2°, and/or the thread conicity of the thread at the said portion/tip (3a) is of the order of 0.4 - 0.8 mm or with an angle of inclination (β) of about 10 - 15°, and the portion/tip has a length or height (h) of about 10 -
20 30% of the length (L) of the threaded part of the implant.

5. Implant according to claim 1, characterized in
25 that the implant threading along at least part of the longitudinal direction of the implant is given a noncircular or eccentric configuration (8a-8i) for the purpose of obtaining improved rotational stability of the implant in the recently inserted
30 state or the incorporated state of the implant in soft/weak bone.

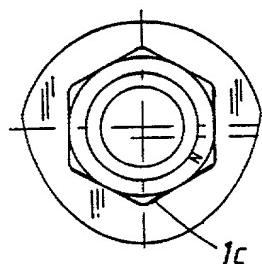
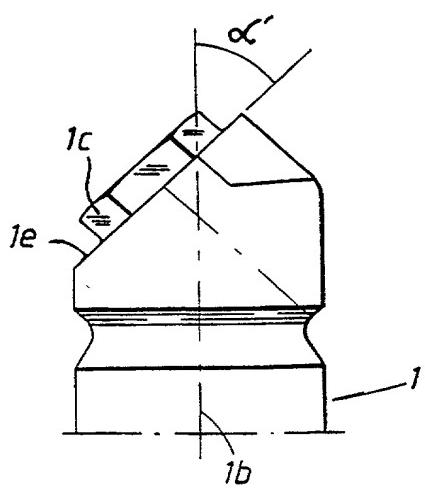
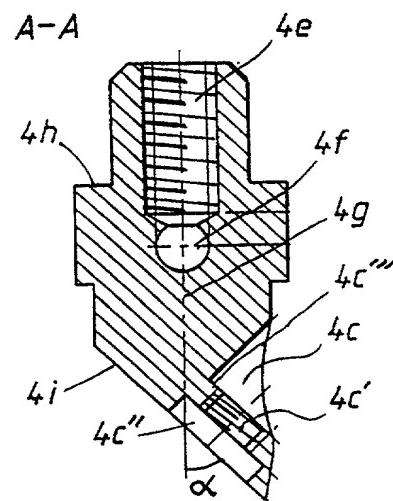
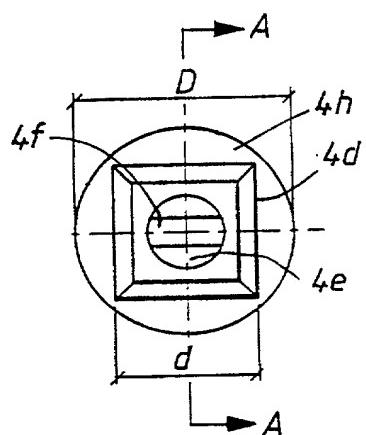
6. Implant according to claim 5, characterized in
35 that the implant is arranged with a minimum diameter (D') which corresponds to or is slightly greater, for example 1 - 5% greater, than the diameter (d) of the hole.

7. Implant according to claim 1 or any of claims 5-6, characterized in that the tip or the free end of the implant has a circular or concentric thread (3e) which merges gradually into a non-circular or 5 eccentric thread on the remaining part or parts of the implant.
8. Implant according to claim 1 or any of claims 5-7, characterized in that the peripheris of the different non-circular or eccentric thread cross-sections have bevelled corners (12) in order to 10 avoid sharp corners.
9. Implant according to claim 1 or any of claims 5-15, characterized in that the non-circularity is arranged such that areas of maximum diameter are displaced in the peripheral direction from one thread turn (10) to the next thread turn (11).
- 20 10. Implant according to claim 1, characterized in that the number of thread spirals/thread entries is two, three or four.
- 25 11. Implant according to claim 10, characterized in that the number of thread spirals/thread entries is adapted to the number of cutting edges (5a, 5b, 5c, 5d) so that symmetrical cutting forces are obtained.
- 30 12. Implant according to claim 10 or 11, characterized in that two thread spirals are arranged on the implant together with two or four cutting edges, or in that three thread spirals are arranged together with three cutting edges, etc.

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Fig. 1Fig. 2

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DECLARATION FOR PATENT APPLICATION

Page Two

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